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Response Under 37 CFR §1.116
Expedited Procedure
Examining Group 1626

CASE QA0238 NP

#9

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
BARRISH ET AL.
APPLICATION NO: 10/027,982
FILED: DECEMBER 20, 2001
FOR: THIAZOLYL INHIBITORS OF TEC FAMILY TYROSINE KINASES

Art Unit: 1626
Examiner: Rebecca L. Anderson

Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

01/29/2003 [illegible]
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PETITION PURSUANT TO 37 C.F.R. §1.144

Sir:

Applicants herein petition the Commissioner from the Examiner's final restriction requirement dated November 5, 2002. The basis for this petition is set forth in detail below.

Applicants believe that no fee is due, as 37 C.F.R. §1.144 does not provide for the payment of a fee. However, in the event that a fee is deemed required please charge the appropriate amount to Deposit Account No. 19-3880 in the name of Bristol-Myers Squibb Company.

I. BACKGROUND

By Office Action dated March 11, 2002 the Examiner issued a restriction requirement. This restriction requirement set forth two purportedly distinct inventions: (1) compounds/products of formula I (invention Group I), and (2) methods of use for compounds/products of formula I (invention Group II). The restriction requirement further stated that upon electing an invention group Applicants were required to elect a single disclosed species. The restriction requirement did not attempt to specifically identify any distinct inventions within invention Group I. However, the restriction requirement vaguely stated:

> "Claims 1 and 20 are generic to a plurality of disclosed patentably distinct species comprising, for example, the

compounds of (1) Example 62, page 84, (2) Example 58, page 84, etc. ..."

(March 11 Office Action, page 2 lines 15-17).

On April 11, 2002 Applicants responded to the restriction requirement (with traverse), electing invention group I, and further selecting the compound of Example 76 as the single disclosed species.

By Office Action dated May 10, 2002 the Examiner indicated that a search on the selected species did not reveal any invalidating art. The Examiner indicated that claims would be allowed **provided** they were re-cast into a "generic concept" arbitrarily formulated by the Examiner. This "generic concept" very narrowly defined compounds extremely similar to the single selected species.

On August 9, 2002 Applicants responded to the Office Action by narrowing the claims considerably. Applicants requested that the Examiner consider these narrowed claims on the basis that the "generic concept" was overly narrow and that the Examiner's arbitrary recasting of the claims constituted an improper refusal to examine that which the Applicants regard as their invention.

By Final Action dated November 5, 2002 the Examiner refused to allow any claim broader than the narrow "generic concept" set forth in the Office Action dated May 10, 2002. In support of this position the Examiner states:

- 35 U.S.C. §121 gives the Commissioner authority to limit the examination of an application where two or more distinct inventions are claimed (see Final Action at page 3 lines 15-18); and
- Applicants have not provided any reasons why the claims do not involve independent or distinct inventions (see Final Action at page 4 lines 1-2).

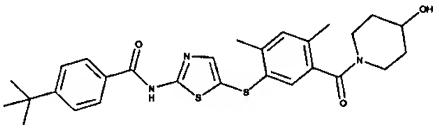
In their response to the Final Action (submitted concurrently herewith) Applicants have requested that amendments be entered that even further limit the claims—but which provide a fairer scope than the overly narrow "generic concept" formulated by the Examiner.

II. ARGUMENT

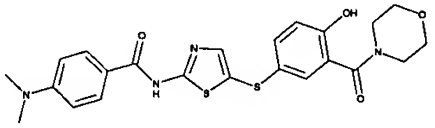
Applicants respectfully submit that the procedures employed by the Examiner are improper and result in a refusal to examine that which the Applicants regard as their invention.

A. The r striction requirement never adequately support d the Examiner's assertion that the application disclosed patentably distinct species

The Examiner's initial restriction requirement never set forth any basis for explaining the Examiner's assertion that the application disclosed patentably distinct species. Rather, the Examiner merely stated that "for example, the compounds of (1) Example 62 ..., [and] (2) Example 58 ...etc." were patentably distinct. The two compounds identified by the Examiner are shown below:



EXAMPLE 58



EXAMPLE 62

Applicants believe that a single search could uncover relevant art for either compound. Applicants are not aware of any patentable distinction between these two compounds.

What makes these two compounds patentably distinct? The Examiner never explains. Applicants were simply left to guess (1) the basis upon the Examiner had reached this conclusion; and (2) how many different purportedly "distinct" species actually existed. Applicants still do not understand what the Examiner means or how many purportedly patentably distinct species are purportedly disclosed. Now the Examiner requires Applicants to provide affirmative evidence/support of a *negative* proposition to rebut an affirmative position that has never been clearly put forward in the first place (see page 4 of Final Action).

The restriction procedure employed by the Examiner prevented Applicants from making a meaning election. The Examiner in essence said "select a single compound now and I will tell you (later—after the fact) what the invention group consists of." This improper procedure prejudices Applicants attempt to have meaningful claims examined.

B. Th "gen ric concept" arbitrarily created by the Examiner is overly narrow

The "generic concept" arbitrarily created by the Examiner is clearly over-narrow. For example:

- As originally described by Applicants the thio-phenyl group can contain up to three optional substituents (R_{1ab}, R_{1ac} and R_{1ac}) (see e.g., original claim 7), yet the Examiner's "generic concept" only allows for two groups (and severely limits what these substituents can be). The Examiner never states that an additional third substituent on the phenyl (or substituent groups other than those included in the "generic concept") makes the resulting compound patentably distinct.
- The Examiner's "generic concept" severely limits what the R_2 and R_3 groups can be—despite the existence of numerous additional groups exemplified throughout the application.
- The Examiner's "generic concept" limits the Z_3 substituent on the piperazine ring to the specific substituent used in the single elected species—despite numerous additional substituent groups exemplified throughout the application (see, e.g. examples 17, 19, 32, 38, 39, 40, 237, 238, 248 etc.). Yet the Examiner never asserts that different Z_3 groups would render the resulting compound patentably distinct from the selected species.

The Examiner's "generic concept" is basically a "bullet claim" limited to Applicants' selected species. This restriction procedure violates 37 C.F.R. § 1.146, which provides that Applicants are entitled to claim a reasonable number of species. Applicants respectfully submit that the "generic concept" formulated by the Examiner does **not** encompass a reasonable number of species.

III. Request d Relief

Applicants request that the Commissioner direct the Examiner to enter the amendments proposed in Applicants' response to the Final Action, so that a reasonable number of species can be covered in the claims.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-5781

Ronald S. Hermenau
Attorney for Applicants
Reg. No. 34,620

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